UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Mitsubishi Chemical Corporation, Mitsubishi Tanabe Pharma Corporation, Encysive Pharmaceuticals Inc., Glaxo Group Limited, and SmithKline Beecham plc,	)	Civil Action No. 07 CV 11614
	)	**Electronically Filed**
	)	Hon. Judge Koeltl
Plaintiffs,	)	
v.	)	**NOTICE OF MOTION AND MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT**
Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o.	)	
Defendants.	)	

PLEASE TAKE NOTICE that, upon this notice, the accompanying memorandum of law, the papers on file in this action, any oral argument given at a hearing on the motion, and any other matter that the Court deems appropriate, plaintiffs Glaxo Group Limited and SmithKline Beecham plc, will move the Court, before the Honorable John G. Koeltl, United States District Court for the Southern District of New York, Daniel Patrick Moynihan United States Courthouse, 500 Pearl St., Room 1030, New York, New York, at a time and date convenient for the Court, for an order pursuant to Federal Rules of Civil Procedure 15(a) and 21 for leave to file a Second Amended Complaint adding SmithKline Beecham Corp. d/b/a GlaxoSmithKline as a party plaintiff.

The proposed new pleading is attached to this motion as **Exhibit A**. A blacklined version of the pleading comparing the existing version of the pleading with the proposed new pleading is attached hereto as **Exhibit B**.

Respectfully submitted,

Dated: February 29, 2008

/s/ Robert J. Gunther, Jr.
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Glaxo Group Limited and SmithKline Beecham plc

CERTIFICATE OF SERVICE

I, Robert J. Gunther, an attorney at law admitted to practice before this Court certify that on this 29th day of February, 2008, I caused to be served via ECF the plaintiffs' Notice of Motion and Motion for Leave to File a Second Amended Complaint on all counsel of record.

/s/ Robert J. Gunther, Jr.
Robert J. Gunther, Esq.

Exhibit A

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Mitsubishi Chemical Corporation, Mitsubishi Tanabe Pharma Corporation, Encysive Pharmaceuticals Inc., Glaxo Group Limited, SmithKline Beecham plc, and SmithKlineBeecham Corp. d/b/a GlaxoSmithKline,	)	Civil Action No. 07 CV 11614
	)	Hon. Judge Koeltl
Plaintiffs,	)	**[PROPOSED] SECOND AMENDED COMPLAINT**
v.	)	
Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o.	)	
Defendants.	)	

Plaintiffs, Mitsubishi Chemical Corporation ("MCC"), Mitsubishi Tanabe Pharma Corporation ("MTPC"), Encysive Pharmaceuticals Inc. ("Encysive"), Glaxo Group Limited ("GGL"), SmithKline Beecham plc ("SKB plc"), and SmithKline Beecham Corp. d/b/a GlaxoSmithKline ("SKB Corp.") (collectively "GSK") (collectively, "Plaintiffs"), by their counsel, for their Complaint against defendants Barr Laboratories, Inc. ("Barr") and Pliva-Hrvatska d.o.o. ("Pliva") (collectively, "Defendants") allege as follows:

Jurisdiction and Venue

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, and arising under 35 U.S.C. §§ 271(e)(2), 271(b), 271(c) and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(d) and 1400(b). Personal jurisdiction over the Defendants in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a).

The Parties

2. MCC is a Japanese corporation having its corporate headquarters and principal place of business in Tokyo, Japan. MCC is engaged in the business of employing the science of chemistry to create, develop, and improve products with a particular focus in the areas of petrochemicals, performance and functional products, and health care.

3. MTPC is a Japanese corporation having its corporate headquarters and principal place of business in Osaka, Japan. MTPC is a pharmaceutical company that engages in the development, manufacture, and marketing of a broad spectrum of innovative pharmaceutical products.

4. Encysive is a Delaware corporation having its corporate headquarters and principal place of business in Houston, Texas. Encysive is a biopharmaceutical company engaged in the discovery, development, and commercialization of novel compounds to address unmet medical needs.

5. GGL is a company organized and existing under the laws of England and Wales having its registered office in Greenford, England. SKB plc is a Company organized and existing under the laws of England and Wales having its registered office in Brentford, England. SKB Corp. is a Pennsylvania corporation having a principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania.

6. Upon information and belief, Barr is a Delaware corporation with corporate headquarters in Pomona, New York. Upon information and belief, Barr is in the business of manufacturing and marketing generic pharmaceuticals. Upon information and belief, Barr is registered with the New York Department of State, Division of Corporations, to do business in New York as a foreign corporation.

7. Upon information and belief, Pliva is a European generic pharmaceutical company with a place of business in Zagreb, Croatia. Upon information and belief, Barr is authorized to accept service of process for Pliva at 223 Quaker Road, P.O. Box 2900, Pomona, New York 10970.

8. Upon information and belief, Abbreviated New Drug Application ("ANDA") No. 79-238 was submitted on behalf of Pliva to the United States Food and Drug Administration.

9. Upon information and belief, Pliva and Barr do business in the Southern District of New York and, by filing ANDA No. 79-238, have committed a tortious act outside the state of New York that Pliva and Barr expect or should reasonably expect to have consequences in the state.

10. United States Patent No. 5,214,052 ("the '052 Patent"), entitled "Method for Dissolving Arginineamides and Pharmaceutical Compositions Containing Them," a true and correct copy of which is appended hereto as Exhibit A, was duly issued on May 25, 1993 to inventors Kunihiko Ofuchi and Tatsuo Nomura, and assigned to MCC (then known as Mitsubishi Kasei Corporation). The '052 Patent claims, *inter alia*, a novel injectable pharmaceutical composition comprising 1-[5-[(aminoiminomethyl)amino]-1-oxo-2-[[(1,2,3,4-tetrahydro-3-methyl-8-quinolinyl)sulfonyl]amino]pentyl]-4-methyl-2-piperidinecarboxylic acid, monohydrate ("Argatroban") dissolved in a solvent containing ethanol, water, and a saccharide ("Argatroban Injection") as well as the method of preparation of Argatroban Injection.

11. MCC has been and is the owner of the '052 Patent which expires on June 30, 2014, having received a patent term extension pursuant to 35 U.S.C. § 156.

12. MTPC is the successor in interest to certain rights in MCC's pharmaceutical business including rights relating to Argatroban Injection, and holds an exclusive license to the '052 Patent with the right to sublicense, as well as certain rights under a license agreement relating to Argatroban Injection between MCC and Encysive.

13. Encysive holds an exclusive sublicense to the '052 Patent for the United States territory. Encysive's exclusive sublicense includes the right to further sublicense. Encysive is also the holder of the approved new drug application ("NDA") for Argatroban Injection.

14. GGL, SKB plc and SKB Corp. each hold an exclusive license to the '052 Patent for sale of Argatroban Injection in the United States.

15. Plaintiffs will be both substantially and irreparably harmed by infringement of the '052 Patent. There is no adequate remedy at law.

The New Drug Application

16. SKB Corp. sells Argatroban Injection in the United States pursuant to the United States Food and Drug Administration's approval of an NDA held by Encysive. The NDA for Argatroban Injection, NDA No. 020883, was approved on June 30, 2000.

17. Argatroban Injection is an anticoagulant that is approved for use including prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia.

COUNT I
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(e)(2)(A) BY DEFENDANT)

18. Plaintiffs repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 17 above.

19. Defendants filed ANDA No. 79-238 with the Food and Drug Administration ("FDA") seeking approval under 21 U.S.C. § 355(j) to market generic Argatroban Injection.

20. By this ANDA filing, Defendants have indicated that they intend to engage in, and that there is substantial likelihood that they will engage in, the commercial manufacture, use, offer for sale, sale, and/or importation of the patented product immediately or imminently upon receiving FDA approval to do so. Also by Defendants' ANDA filing, Defendants indicated that the drug product for which they seek FDA approval (the "Proposed Product") is bioequivalent to Argatroban Injection.

21. By this ANDA filing, Defendants seeks to obtain approval to commercially manufacture, use, offer for sale, sell, and/or import alleged generic equivalents of Argatroban Injection prior to the expiration date of the '052 Patent.

22. By a letter dated November 16, 2007 (the "First Notice Letter"), defendant Barr informed Plaintiffs that it had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about November 19, 2007, patent owner MCC received a copy of the First Notice Letter. On or about November 19, 2007, NDA holder Encysive received a copy of the First Notice Letter.

23. The First Notice Letter, purporting to be a Notice of Certification under 21 U.S.C.§ 355(j)(2)(B), alleges that, in Barr's opinion, "the '052 patent is invalid, unenforceable, or will not be infringed by the manufacture, importation, use or sale of the drug product described in Barr's ANDA."

24. The First Notice letter made no reference to Pliva.

25. By a letter dated January 15, 2008, Defendants advised that, while the First Notice Letter identified Barr as the applicant for ANDA 79-238, the name of the applicant identified in ANDA 79-238 was, in fact, Pliva.

26. By a separate letter, also dated January 15, 2008 (the "Second Notice Letter"), Defendants Pliva and Barr informed Plaintiffs that they had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about January 17, 2008, patent owner MCC received a copy of the Second Notice Letter. On or about January 16, 2008, NDA holder Encysive received a copy of the Second Notice Letter.

27. The Second Notice Letter, purporting to be a Notice of Certification under 21 U.S.C.§ 355(j)(2)(B), alleges that, in Pliva's opinion, "the '052 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, importation, use or sale of the drug product described in the ANDA."

28. Pliva asserts that claims 1 – 4 of the '052 Patent are invalid under 35 U.S.C. § 103(a) in view of two references: Yoshikuni Tamao *et al.*, "Alpha-(N-arylsulfonyl-L-argininamides, Processes for Their Preparation and Pharmaceutical Composition Containing These Substances," European Patent Application No. 79103092.7, and George M. Krause and John M. Cross, "Solubility of Phenobarbital in Alcohol-Glycerin-Water Systems," *Journal of the American Pharmaceutical Association*, Vol. XL:137-139 (1951).

29. The '052 Patent is not invalid under 35 U.S.C. § 103(a).

30. Beyond summarily claiming that "the '052 patent is invalid, unenforceable, and/or will not be infringed by" the Proposed Product, Defendants do not specifically assert that the '052 Patent is unenforceable, and the Letter does not provide any factual or legal basis for an assertion that the '052 Patent is unenforceable, as required by applicable law.

31. Beyond summarily claiming that "the '052 patent is invalid, unenforceable, and/or will not be infringed by" the Proposed Product, Defendants do not specifically assert that the drug product for which it seeks approval would not infringe the '052 Patent, and the Letter does not provide any factual or legal basis for an assertion that the drug product for which Defendants seek approval would not infringe the '052 Patent, as required by applicable law.

32. Beyond summarily claiming that "any available objective evidence of nonobviousness is insufficient to rebut the *prima facie* case of obviousness," Defendants do not provide any analysis of secondary considerations of nonobviousness. The Letter also fails to

provide any factual or legal basis for Defendants assertion that "any available objective evidence of nonobviousness is insufficient to rebut the *prima facie* case of obviousness," as required by applicable law.

33. Defendants' filing of ANDA No. 79-238 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic equivalent of Argatroban Injection before the expiration of the '052 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

34. Defendants' manufacture, use, offer for sale, sale, and/or importation of the Proposed Product will directly infringe at least one of the claims of the '052 Patent.

35. Unless Defendants are enjoined from infringing the '052 Patent, Plaintiffs will suffer substantial and irreparable injury.

36. Plaintiffs have no adequate remedy at law.

COUNT II
(INDUCEMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(b) BY DEFENDANT)

37. Plaintiffs repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 36 above.

38. Upon information and belief, sale of the Proposed Product will induce others to infringe the '052 Patent.

39. Upon information and belief, Defendants know or reasonably should know that sale of the Proposed Product will induce others to infringe the '052 Patent.

40. Upon information and belief, Defendants specifically intend that others will use the Proposed Product to infringe the '052 Patent.

41. Unless Defendants are enjoined from inducing infringement of the '052 Patent, Plaintiffs will suffer substantial and irreparable injury.

42. Plaintiffs have no adequate remedy at law.

COUNT III
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(c) BY DEFENDANT)

43. Plaintiffs repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 42 above.

44. Upon information and belief, the Proposed Product constitutes a material part of the invention disclosed in the ‘052 Patent.

45. Upon information and belief, the Proposed Product will be especially made for use in an infringement of the ‘052 Patent.

46. Upon information and belief, Defendants know that the Proposed Product will be especially made for use in an infringement of the ‘052 Patent.

47. Upon information and belief, sale of the Proposed Product will result in direct infringement of the ‘052 Patent.

48. Upon information and belief, the Proposed Product is not a staple article or commodity of commerce which is suitable for substantial noninfringing use.

49. Upon information and belief, Defendants know that the Proposed Product is not a staple article or commodity of commerce which is suitable for substantial noninfringing use.

50. Unless Defendants are enjoined from contributorily infringing the ‘052 Patent, Plaintiffs will suffer substantial and irreparable injury.

51. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) a judgment that making, using, selling, offering to sell and/or importing Defendants' drug product for which it seeks FDA approval will infringe, induce infringement of, and/or contributorily infringe at least one claim of the '052 Patent;

(b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Defendants' drug product for which it seeks FDA approval will infringe, induce infringement of, and/or contributorily infringe at least one claim of the '052 Patent;

(c) a judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Defendants to commercially make, use, sell, offer to sell or import Defendants' drug product for which it seeks FDA approval be no earlier than the date following the expiration date of the '052 Patent;

(d) a permanent injunction restraining and enjoining against any infringement, inducement of infringement, or contributory infringement by Defendants, their officers, agents, attorneys, and employees and those acting in privity or concert with all or any of them, of the '052 Patent through the commercial manufacture, use, sale, offer for sale or importation into the United States of Defendants' drug product for which it seeks FDA approval;

(e) Attorneys' fees in this action under 35 U.S.C. § 285;

(f) Such further and other relief as this Court may deem just and proper.

Dated: New York, N.Y.
February 29, 2008

_____
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Exhibit B

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Robert J. Gunther, Jr.
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and SmithKlineBeecham Corp. d/b/a GlaxoSmithKline
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Mitsubishi Chemical Corporation, Mitsubishi Tanabe Pharma Corporation, Encysive Pharmaceuticals Inc., Glaxo Group Limited ~~and~~, SmithKline Beecham plc, and SmithKlineBeecham Corp. d/b/a GlaxoSmithKline, Plaintiffs, v. Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o. Defendants.	Civil Action No. 07 CV 11614 Hon. Judge Koeltl ~~**FIRST**~~**SECOND AMENDED COMPLAINT**

Plaintiffs, Mitsubishi Chemical Corporation ("MCC"), Mitsubishi Tanabe Pharma Corporation ("MTPC"), Encysive Pharmaceuticals Inc. ("Encysive"), Glaxo Group Limited ("GGL"), SmithKline Beecham plc ("SKB plc"), and SmithKline Beecham ~~plc~~Corp. d/b/a GlaxoSmithKline ("SKB ~~plc~~Corp.") (collectively "GSK") (collectively, "Plaintiffs"), by their counsel, for their Complaint against defendants Barr Laboratories, Inc. ("Barr") and Pliva-Hrvatska d.o.o. ("Pliva") (collectively, "Defendants") allege as follows:

Jurisdiction and Venue

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, and arising under 35 U.S.C. §§ 271(e)(2), 271(b), 271(c) and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(d) and 1400(b). Personal jurisdiction over the Defendants in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a).

The Parties

2. MCC is a Japanese corporation having its corporate headquarters and principal place of business in Tokyo, Japan. MCC is engaged in the business of employing the science of chemistry to create, develop, and improve products with a particular focus in the areas of petrochemicals, performance and functional products, and health care.

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8. Upon information and belief, Abbreviated New Drug Application ("ANDA") No. 79-238 was submitted on behalf of Pliva to the United States Food and Drug Administration.

9. Upon information and belief, Pliva and Barr do business in the Southern District of New York and, by filing ANDA No. 79-238, have committed a tortious act outside the state of New York that Pliva and Barr expect or should reasonably expect to have consequences in the state.

10. United States Patent No. 5,214,052 ("the '052 Patent"), entitled "Method for Dissolving Arginineamides and Pharmaceutical Compositions Containing Them," a true and correct copy of which is appended hereto as Exhibit A, was duly issued on May 25, 1993 to inventors Kunihiko Ofuchi and Tatsuo Nomura, and assigned to MCC (then known as Mitsubishi Kasei Corporation). The '052 Patent claims, *inter alia*, a novel injectable pharmaceutical composition comprising 1-[5-[(aminoiminomethyl)amino]-1-oxo-2-[[(1,2,3,4-tetrahydro-3-methyl-8-quinolinyl)sulfonyl]amino]pentyl]-4-methyl-2-piperidinecarboxylic acid, monohydrate ("Argatroban") dissolved in a solvent containing ethanol, water, and a saccharide ("Argatroban Injection") as well as the method of preparation of Argatroban Injection.

11. MCC has been and is the owner of the '052 Patent which expires on June 30, 2014, having received a patent term extension pursuant to 35 U.S.C. § 156.

12. MTPC is the successor in interest to certain rights in MCC's pharmaceutical business including rights relating to Argatroban Injection, and holds an exclusive license to the '052 Patent with the right to sublicense, as well as certain rights under a license agreement relating to Argatroban Injection between MCC and Encysive.

13. Encysive holds an exclusive sublicense to the '052 Patent for the United States territory. Encysive's exclusive sublicense includes the right to further sublicense. Encysive is also the holder of the approved new drug application ("NDA") for Argatroban Injection.

14. ~~GSK has~~GGL, SKB plc and SKB Corp. each hold an exclusive license to the '052 Patent for sale of Argatroban Injection in the United States.

15. Plaintiffs will be both substantially and irreparably harmed by infringement of the '052 Patent. There is no adequate remedy at law.

The New Drug Application

16. ~~GSK~~SKB Corp. sells Argatroban Injection in the United States pursuant to the United States Food and Drug Administration's approval of an NDA held by Encysive. The NDA for Argatroban Injection, NDA No. 020883, was approved on June 30, 2000.

17. Argatroban Injection is an anticoagulant that is approved for use including prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia.

COUNT I
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(e)(2)(A) BY DEFENDANT)

18. Plaintiffs repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 17 above.

19. Defendants filed ANDA No. 79-238 with the Food and Drug Administration ("FDA") seeking approval under 21 U.S.C. § 355(j) to market generic Argatroban Injection.

20. By this ANDA filing, Defendants have indicated that they intend to engage in, and that there is substantial likelihood that they will engage in, the commercial manufacture, use, offer for sale, sale, and/or importation of the patented product immediately or imminently upon receiving FDA approval to do so. Also by Defendants' ANDA filing, Defendants indicated that the drug product for which they seek FDA approval (the "Proposed Product") is bioequivalent to Argatroban Injection.

21. By this ANDA filing, Defendants seeks to obtain approval to commercially manufacture, use, offer for sale, sell, and/or import alleged generic equivalents of Argatroban Injection prior to the expiration date of the '052 Patent.

22. By a letter dated November 16, 2007 (the "First Notice Letter"), defendant Barr informed Plaintiffs that it had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about November 19, 2007, patent owner MCC received a copy of the First Notice Letter. On or about November 19, 2007, NDA holder Encysive received a copy of the First Notice Letter.

23. The First Notice Letter, purporting to be a Notice of Certification under 21 U.S.C.§ 355(j)(2)(B), alleges that, in Barr's opinion, "the '052 patent is invalid, unenforceable, or will not be infringed by the manufacture, importation, use or sale of the drug product described in Barr's ANDA."

24. The First Notice letter made no reference to Pliva.

25. By a letter dated January 15, 2008, Defendants advised that, while the First Notice Letter identified Barr as the applicant for ANDA 79-238, the name of the applicant identified in ANDA 79-238 was, in fact, Pliva.

26. By a separate letter, also dated January 15, 2008 (the "Second Notice Letter"), Defendants Pliva and Barr informed Plaintiffs that they had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about January 17, 2008, patent owner MCC received a copy of the Second Notice Letter. On or about January 16, 2008, NDA holder Encysive received a copy of the Second Notice Letter.

27. The Second Notice Letter, purporting to be a Notice of Certification under 21 U.S.C.§ 355(j)(2)(B), alleges that, in Pliva's opinion, "the '052 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, importation, use or sale of the drug product described in the ANDA."

28. Pliva asserts that claims 1 – 4 of the '052 Patent are invalid under 35 U.S.C. § 103(a) in view of two references: Yoshikuni Tamao *et al.*, "Alpha-(N-arylsulfonyl-L-argininamides, Processes for Their Preparation and Pharmaceutical Composition Containing These Substances," European Patent Application No. 79103092.7, and George M. Krause and John M. Cross, "Solubility of Phenobarbital in Alcohol-Glycerin-Water Systems," *Journal of the American Pharmaceutical Association*, Vol. XL:137-139 (1951).

29. The '052 Patent is not invalid under 35 U.S.C. § 103(a).

30. Beyond summarily claiming that "the '052 patent is invalid, unenforceable, and/or will not be infringed by" the Proposed Product, Defendants do not specifically assert that the '052 Patent is unenforceable, and the Letter does not provide any factual or legal basis for an assertion that the '052 Patent is unenforceable, as required by applicable law.

31. Beyond summarily claiming that "the '052 patent is invalid, unenforceable, and/or will not be infringed by" the Proposed Product, Defendants do not specifically assert that the drug product for which it seeks approval would not infringe the '052 Patent, and the Letter does not provide any factual or legal basis for an assertion that the drug product for which Defendants seek approval would not infringe the '052 Patent, as required by applicable law.

32. Beyond summarily claiming that "any available objective evidence of nonobviousness is insufficient to rebut the *prima facie* case of obviousness," Defendants do not provide any analysis of secondary considerations of nonobviousness. The Letter also fails to

provide any factual or legal basis for Defendants assertion that "any available objective evidence of nonobviousness is insufficient to rebut the *prima facie* case of obviousness," as required by applicable law.

33. Defendants' filing of ANDA No. 79-238 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic equivalent of Argatroban Injection before the expiration of the '052 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

34. Defendants' manufacture, use, offer for sale, sale, and/or importation of the Proposed Product will directly infringe at least one of the claims of the '052 Patent.

35. Unless Defendants are enjoined from infringing the '052 Patent, Plaintiffs will suffer substantial and irreparable injury.

36. Plaintiffs have no adequate remedy at law.

COUNT II
(INDUCEMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(b) BY DEFENDANT)

37. Plaintiffs repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 36 above.

38. Upon information and belief, sale of the Proposed Product will induce others to infringe the '052 Patent.

39. Upon information and belief, Defendants know or reasonably should know that sale of the Proposed Product will induce others to infringe the '052 Patent.

40. Upon information and belief, Defendants specifically intend that others will use the Proposed Product to infringe the '052 Patent.

41. Unless Defendants are enjoined from inducing infringement of the ‘052 Patent, Plaintiffs will suffer substantial and irreparable injury.

42. Plaintiffs have no adequate remedy at law.

COUNT III
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(c) BY DEFENDANT)

43. Plaintiffs repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 42 above.

44. Upon information and belief, the Proposed Product constitutes a material part of the invention disclosed in the ‘052 Patent.

45. Upon information and belief, the Proposed Product will be especially made for use in an infringement of the ‘052 Patent.

46. Upon information and belief, Defendants know that the Proposed Product will be especially made for use in an infringement of the ‘052 Patent.

47. Upon information and belief, sale of the Proposed Product will result in direct infringement of the ‘052 Patent.

48. Upon information and belief, the Proposed Product is not a staple article or commodity of commerce which is suitable for substantial noninfringing use.

49. Upon information and belief, Defendants know that the Proposed Product is not a staple article or commodity of commerce which is suitable for substantial noninfringing use.

50. Unless Defendants are enjoined from contributorily infringing the ‘052 Patent, Plaintiffs will suffer substantial and irreparable injury.

51. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) a judgment that making, using, selling, offering to sell and/or importing Defendants' drug product for which it seeks FDA approval will infringe, induce infringement of, and/or contributorily infringe at least one claim of the '052 Patent;

(b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Defendants' drug product for which it seeks FDA approval will infringe, induce infringement of, and/or contributorily infringe at least one claim of the '052 Patent;

(c) a judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Defendants to commercially make, use, sell, offer to sell or import Defendants' drug product for which it seeks FDA approval be no earlier than the date following the expiration date of the '052 Patent;

(d) a permanent injunction restraining and enjoining against any infringement, inducement of infringement, or contributory infringement by Defendants, their officers, agents, attorneys, and employees and those acting in privity or concert with all or any of them, of the '052 Patent through the commercial manufacture, use, sale, offer for sale or importation into the United States of Defendants' drug product for which it seeks FDA approval;

(e) Attorneys' fees in this action under 35 U.S.C. § 285;

(f) Such further and other relief as this Court may deem just and proper.

Dated: New York, N.Y.
February ~~21,~~29, 2008

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Mitsubishi Chemical Corporation, Mitsubishi Tanabe Pharma Corporation, Encysive Pharmaceuticals Inc., Glaxo Group Limited, and SmithKline Beecham plc, Plaintiffs, v. Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o. Defendants.	Civil Action No. 07 CV 11614 **Electronically Filed** Hon. Judge Koeltl **[PROPOSED] ORDER GRANTING MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT**

Plaintiffs Glaxo Group Limited's and SmithKline Beecham plc's (together "Plaintiffs") Motion for Leave to File a Second Amended Complaint came before this Court, and having read and considered the motion and the supporting documents thereto, and any opposition and supporting documents filed thereto, the Court GRANTS the Motion.

IT IS HEREBY ORDERED THAT Plaintiffs' Motion for Leave to File a Second Amended is GRANTED.

IT IS FURTHER ORDERED THAT the Second Amended Complaint attached as Exhibit A to Plaintiffs' Notice of Motion and Motion for Leave to File a Second Amended Complaint is deemed filed and served.

IT IS, on this _____ day of _____, 2008,

ORDERED THAT the motion be, and is hereby GRANTED.